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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,782	05/26/2005	Jorgen Rasmussen	Patradc	6076
<div>James C Wray Suite 300 1493 Chain Bridge Road McLean, VA 22101</div>				
<div>7590 01/04/2008</div>			<div>EXAMINER OSTRUP, CLINTON T</div>	
			<div>ART UNIT 3771</div>	<div>PAPER NUMBER</div>
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/533,782	RASMUSSEN ET AL.	
	Examiner	Art Unit	
	Clinton Ostrup	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 7/1/05.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☒ Claim(s) 1-16 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 May 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/1/2005</u>  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Claims 1-16 are pending in this application.

#### ***Priority***

The examiner acknowledges this application was filed as a United States National Phase Application of International Application Serial No. PCT/DK2003/00749 filed November 1, 2003, which claims priority from Denmark application Nos. PA 2002 019694, filed November 4, 2002; PA 2002 01695, filed November 4, 2002; PA 2003 00429, filed March 20, 2003; and PA 2003 01053, filed July 11, 2003.

#### ***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "dose counting mechanism arranged in the housing" must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering

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of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Specification***

The disclosure is objected to because of the following informalities: Page 2, line 4 refers to EP 476991 and then on line 12 it refers to EP 176991. For examination purposes, it was assumed applicant intended to refer to EP 476991 in both instances, however, appropriate correction is required.

### ***Claim Objections***

Claims 1-16 are objected to because of the following informalities:

In the claims, when the term "the" or "said" is used, the word following the term "the" or "said" must have proper antecedent basis. The claims are replete with terms "the" and "said" referring to limitations not having proper antecedent basis.

For example, claim 1 recites the limitations "said device," "the canister," "the bottom," "the transfer," and "the activation;" however, claim 1 lacks antecedent basis for these limitations. Claim 1 provides antecedent basis for "inhaler device" and "pressurized canister" and applicant is reminded to be consistent in their terminology.

In claim 2 is objected to for analogous reasons to the objection of claim 1 and further because of the term "that." It appears this was a typo and the term "that" was intended to be "than."

Claims 3-16 are objected to for analogous reasons to the objection of claim 1, as there is a lack of antecedent basis for claim limitations and applicant has not been consistent in their terminology.

Claim 7 is further objected to because of the term "in" on line 5. It appears this again was a typo. Appropriate correction is required.

***Claim Rejections - 35 USC § 112 – First Paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2 and 7-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, because the specification does not reasonable enable, "linear and/or non-linear" transfer of movement. However, the specification does provide enablement for the linear and linear and non-linear transfer of movement. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

In regard to the instantly claimed linear and/or non-linear transfer of movement, the specification and drawings do provide for the transfer of both linear and linear and non-linear movement; however they do not provide for only the transfer of non-linear movement. The specification and drawing show a yoke in a vertical, linear position and a lever arm in an angled linear position. The specification and drawings show that upon

activation of the lever arm, the yoke moves in a linear, vertical manner and that the lever arm, which is linear, moves linearly as it is guided by linear and non-linear tracks.

Since the transfer of only non-linear movement is not reasonably enabled by the specification or the drawings and it would require undue experimentation to make an inhaler device with only non-linear transfer of movement, the inhaler device as claimed in claim 1 is not reasonably enabled to the scope it is claimed.

Any remaining claims are rejected as depending from a rejected base claim.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 3 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Bruna et al., (5,692,492).**

The Bruna et al., reference teaches an inhaler device for dispensing a medicament from a pressurized canister (1), where said canister (1) comprises a bottom and a top, and that a valve mechanism (2) is provided in the top of said canister (1) for dispensing a medicament and that in use the canister is placed with the top downwards proximate a mouthpiece (5), where the device comprises a mouthpiece (5) and a means for guiding and/or holding the canister (22), and a lever arm (6) comprising means (91a, 91b) for engagement with the bottom end of the canister (1), such that the canister (1) is not accessible from the outside, and further that a seat for engagement with the top of

the canister (1) is provided inside the housing (38), and a cap (6) is pivotally arranged such that the cap (6) can be pivoted into a closed position where it covers the mouthpiece (5) and an open position where the mouthpiece (5) is accessible, and that said cap (6) further comprises means for abutting the top of the canister and/or for abutting the means (7) for engagement with the bottom end of the canister (91a) when the cap (6) is in its closed position such that the canister (1) cannot be activated accidentally. See: col. 1, lines 4-8; col. 11, lines 1-43 and Figure 14.

Regarding claim 6, Bruna et al., teach a device with a lever arm characterized in that the length of the lever arm (6) is such that when the cap (6) is closed the free end of the lever arm (6) is flush with or contained within the housing, and when the cap (6) is opened the free end of the lever arm (6) will project from the housing (21).

Therefore, Bruna et al., clearly teach the limitations of claims 3 and 6 when the claim is read in the alternative for the cap abutting means and when the lever can also be the cap.

**Claims 3 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Bacon (4,447,150).**

In regard to claim 3, Bacon teaches an inhaler device for dispensing a medicament from a pressurized canister (25), where said canister (25) comprises a bottom and a top, and that a valve mechanism (40) is provided in the top of said canister (25) for dispensing a medicament and that in use the canister is placed with the top downwards proximate a mouthpiece (405), where the device comprises a mouthpiece (405) and a means for guiding and/or holding the canister (420), and a lever

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arm (550) comprising means (540) for engagement with the bottom end of the canister (25), such that the canister (25) is not accessible from the outside, and further that a seat for engagement with the top of the canister (45) is provided inside the housing (400), and a cap (510) is pivotally arranged such that the cap (510) can be pivoted into a closed position where it covers the mouthpiece (405) and an open position where the mouthpiece (405) is accessible, and that said cap (510) further comprises means for abutting the top of the canister (530) **and/or** for abutting the means (540) for engagement with the bottom end of the canister (540) when the cap (510) is in its closed position such that the canister (25) cannot be activated accidentally. See: col. 1, line 64 - col. 2, line 5; col. 5, line 53 – col. 8, line 12; and Figures 3 & 5.

In regard to claim 4, Bacon teaches an aerosol device that has a means for engagement with the bottom of the canister comprising a yoke (530) which yoke has a canister engagement section (420) optionally having a shape corresponding to the bottom of the canister (25), and an end section, which when the cap (510) is in its closed position engages a cam (520) provided on the cap (510), such that the engagement section (420) of the yoke (530) is not in contact with the canister (25). See: col. 6, line 1 – col. 7, line 28. Therefore, Bacon teaches the device of claims 3 and 4 when the lever (550) is located within the device.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and



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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 1-3, 6-8 and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bruna (5,692,492) as applied to claims 3 and 4 above, and further in view of Rand et al., (6,360,739).**

Bruna teaches an inhaler device (Figure 14) for dispensing a medicament from a pressurized canister (1), where said device comprises a mouthpiece (5) arranged in a housing (21), where said housing (21) substantially encloses the canister (1), where a lever arm (6) is provided, where said lever arm (6) comprises means (91a and 91b) for engaging the bottom of the canister (1) such that said lever arm (6) may be activated by a user in order to dispense a dose, characterized in that the lever arm (6) further engages a yoke (7) where the transfer of movement from said lever arm (6) due to the activation of said lever arm to the yoke (7) is linear and/or non-linear.

Bruna et al., teach an inhaler device (Figure 14) meeting the limitations when the claim is read in the alternative for the cap abutting means and when the lever can also be the cap. The Bruna et al., reference teaches an inhaler device for dispensing a medicament from a pressurized canister (1), where said canister (1) comprises a bottom and a top, and that a valve mechanism (2) is provided in the top of said canister (1) for dispensing a medicament and that in use the canister is placed with the top downwards proximate a mouthpiece (5), where the device comprises a mouthpiece (5) and a means for guiding and/or holding the canister (22), and a lever arm (6) comprising means (91a, 91b) for engagement with the bottom end of the canister (1), such that the canister (1) is not accessible from the outside, and further that a seat for engagement with the top of

the canister (1) is provided inside the housing (38), and a cap (6) is pivotally arranged such that the cap (6) can be pivoted into a closed position where it covers the mouthpiece (5) and an open position where the mouthpiece (5) is accessible, and that said cap (6) further comprises means for abutting the top of the canister and/or for abutting the means (7) for engagement with the bottom end of the canister (91a) when the cap (6) is in its closed position such that the canister (1) cannot be activated accidentally. See: col. 1, lines 4-8; col. 11, lines 1-43 and Figure 14.

Bruna et al., teach a device with a lever arm characterized in that the length of the lever arm (6) is such that when the cap (6) is closed the free end of the lever arm (6) is flush with or contained within the housing, and when the cap (6) is opened the free end of the lever arm (6) will project from the housing (21).

However, the Bruna et al., reference lacks yoke means for transferring movement to a dose counting mechanism arranged in the housing as claimed in claims 1-2, 6-8 and 10-13.

Rand et al., teach a metered dose inhaler with a counter that is actuated by the movement of the container relative to the housing, thus teaching the dose counting mechanism of claim 1.

The Rand et al., reference teaches that each time the aerosol dispenser is actuated the star wheel is made to rotate through two incremental anti-clockwise movements. These movements are translated through the counter mechanism into appropriate movements of the digit wheels (33), one number on each of the printed circumferential faces of the digit wheels being clearly visible through the window (20) at

the back of the housing (1), to indicate that a further dose of medicament has been dispensed. Thus, Rand et al teach the claim limitations of claim 8.

Rand et al., teach that the counter mechanism is small enough to be located to the sides of and behind the stem block molded in housing so as not to interfere with the aerosol fume as it emerges. See: col. 7, lines 50-54.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the inhaler device as taught by Bruna et al., by adding the dosage counter as taught by Rand et al., because of the reasonable expectation of obtaining a metered dose inhaler with a dose counter that would provide the user useful information regarding the remaining life of the inhaler product.

**Claims 1-5 and 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bacon (4,447,150) as applied to claims 3 and 4 above, and further in view of O'Leary (2002/0073996 A1).**

Bacon teaches an inhaler device (Figure 3) for dispensing a medicament from a pressurized canister (25), where said device comprises a mouthpiece (405) arranged in a housing (400), where said housing (400) substantially encloses the canister (25), where a lever arm (550) is provided, where said lever arm (550) comprises means (540) for engaging the bottom of the canister (25) such that said lever arm (550) may be activated by a user in order to dispense a dose, characterized in that the lever arm (50) further engages a yoke (530) where the transfer of movement from said lever arm (550) due to the activation of said lever arm to the yoke (530) is linear and/or non-linear. However, the Bacon reference lacks yoke means for transferring movement to a dose

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counting mechanism arranged in the housing as claimed in claims 1-2 & 8 and the three guided tracks as claimed in claim 5.

O'Leary teaches a dose metering system and dose counting system for medicament inhalers. O'Leary teaches that the movement a pivotable mouthpiece cover causes movement of three cam sections on the mouthpiece cover (90, 92, and 94) to make contact with cam followers (78). The cam followers (78) are attached to yokes (66 & 68) and as said yokes move, they cause movement of the counter mechanism in the dose counting system (16). See: page 3 [0043] – 0048]; page 3 [0053] – page 4, [0058]; and Figures 9-15.

The O'Leary reference teaches that the dose counting system (16) is arranged inside the housing and that the housing has a window (130) for indicating the number of doses remaining. See: figure 2.

The O'Leary reference teaches that the dose counting system comprises wheels and spools (128, 132, 134, & 136), which move by means of the yokes connected to the cam followers as the cam followers slide as the mouthpiece cover is opened. See: page 2 [0032] and page 4, [0060] – [0062]

It would have been obvious on one having ordinary skill in the art at the time the invention was made to have modified the metered dose inhaler device as taught by Bacon by adding the dose counting mechanism as taught by O'Leary because of the reasonable expectation of obtaining a metered dose inhaler capable of providing the user with accurate useful life information of a needed product.

**Claims 1 and 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bacon (4,447,150) taken together with O'Leary (2002/0073996 A1) and further in view of Chrstrup et al., (2001/0025639 A1).**

The combined references above teach an inhaler device for dispensing a medicament with a dose counting mechanism as claimed; however, the combination of references lack the return block arrangement as claimed in claims 14-16.

Chrstrup et al., teach a metered dose inhaler with a reset mechanism that includes a track (64) and a toothed rack (72). The Chrstrup et al., reference teaches that the reset mechanism includes a release member (62) mounted on the loading member shaft (32) and that the release member (62) is movable relative to the shaft (32) between limits defined by a pin (63) protruding from the shaft (32) engaging in a track (64) formed in the release member (62). The Chrstrup et al., reference teaches the downwards movement of the release member 62 is damped by a damping element (69) consisting of a stator (70) fixed to the upper housing portion (3) and a rotor (71) rotatable through viscous fluid provided between the rotor (71) and stator (70). The rotor (71) is driven by a toothed rack (72) connected to the release member (62).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the inhaler device with a dose counting mechanism as taught by the combined references above by adding a release mechanism as taught by Chrstrup et al., because of the reasonable expectation of obtaining a metered dose inhaler that would provide a complete dosage of medicament with each actuation of the inhaler.

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**Conclusion**

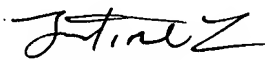
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Clinton Ostrup whose telephone number is (571) 272-5559. The examiner can normally be reached on M-F 7:30-5 pm with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Clinton Ostrup  
Examiner  
Art Unit 3771



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11/2/08